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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,882	02/11/2004	Valeri V. Golovlev	59004.US	3388
408	7590	03/31/2005	EXAMINER	
LUEDEKA, NEELY & GRAHAM, P.C.			DO, PENSEE T	
P O BOX 1871			ART UNIT	
KNOXVILLE, TN 37901			PAPER NUMBER	

1641

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,882	Applicant(s) GOLOVLEV ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 08, 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11-08-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention: - the instant invention is directed to a method of detecting a pattern of the molecular structures on solid support comprising providing a type of colloidal particles, each particle carrying a net charge and is capable of electrostatic interaction with the solid phase and molecular structures of interest; contacting the colloidal particles and the solid support on which said latent pattern of

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molecular structures need be detected; and observing a detectable change brought about by colloidal particles precipitating on the surface of the solid support such that the density of precipitated colloidal particles on the surface follows a pattern of the molecular structures which need to be detected.

The state of the art: - the prior art fails to teach a method for detecting a latent pattern of molecular structures on a solid support by contacting the charged colloidal particles with the solid support on which attached a pattern of molecular structures and observing for a detectable change brought about by colloidal particles precipitated on the surface of the solid support such that the density of precipitated colloidal particles on the surface follows the pattern of molecular structures.

The predictability or lack thereof in the art:- in view of the lack of teachings in the prior art that show or suggests that detection of the pattern of molecular structures on the solid support is possible by contacting the solid support with just colloidal particles, which interacts, with the solid support by electrostatic interaction, the predictability is low.

The amount of direction or guidance present: - the instant specification fails to provide guidance on how just the charged colloidal particles, when electrostatic interact with the solid support with just molecular structures on it, can detect the pattern of molecular structures.

The presence or absence of working examples:- there is no examples in the specification that show detection of the pattern of molecular structures on the solid

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support is possible by contacting the solid support with just a colloidal particles which interacts with the solid support by electrostatic interaction.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed. Since the solid support has molecular structures bound thereto and the colloidal particles interact with the solid support, not the exact position of the molecular structures, signals would form all over the solid support. Thus, there would not be any useful pattern of molecular structures detected.

The relative skill of those in the art: The level of skill in the art is high since one has to figure out how to detect the exact position of the molecular structures through interaction of the solid support and the colloidal particles.

The breadth of the claims: - the claimed method is directed to detection of the latent pattern of molecular structures on the solid support by electrostatic interaction of solid support and the colloidal particles.

Since the claim recites that the colloidal particles interact with the solid support through electric charge, the colloidal particles would only bind to the solid support, not the molecular structures on the solid support. On a solid support where the molecular structures are bound to certain test sites of the solid support, the pattern of the molecular structures must be detected by pinpointing the exact location of the molecular structures bound to the solid support, that is to tag the molecular structures immobilized on the solid phase, not the solid phase. However, according to the recited claims, the colloidal particles target the solid phase only. Thus, there would be signals all over the

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solid support, even on spots where no molecular structures are present. Thus, no meaningful result could be obtained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting "molecular structures" in line 1 and "molecular structures of interest" in line 3. Are these the same or different? See also claim 11 for the same problem.

Claim 1 is indefinite for reciting "the particle ...is capable of electrostatic interaction with the solid support and the molecular structures". How can the particle interact with two different reagents, solid support and the molecular structures while it has only one kind of charge? Are the molecular structures coated on the solid support? If so, to which reagent, the molecular structures or the solid support, does the colloidal particle bind to?

Claim 1 is also unclear of how the molecular structures are detected with just the interaction between the colloidal particle and the solid support. If the colloidal particle interacts directly with the solid support, then there would always be signal regardless of the presence of the molecular structures.

Claim 11 is indefinite. In line 7, it recites that the [alternative binding] agent presents colloidal particles from precipitating while reciting in line 11 that "observing a

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change brought about by colloidal particles precipitated on the surface". This is inconsistent.

Claims 11 and 12 seem to lack a step of measuring the binding rate of colloidal particles and the absorption rate of the alternative binding agent.

Claim 11 is indefinite of where the molecular structures are, on the solid support? Or stand-alone? See also claim 1 for the same issue.

Claim 13 is indefinite for reciting "equally acceptable". What are the metes and bounds of "equally acceptable"?

In claim 13, what is the spatial relationship between the opaque and transparent solid support? "Creating the latent pattern... on ***the solid support..***" which solid support? The opaque or the transparent?

Claim 13, what is the spatial relationship on the solid support between the colloidal particles (on the solid support) and the probe molecular structures (immobilized on the solid support)? See also claim 14 for the same problem.

Regarding claim 14, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as

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to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation "means for keeping the screen", and the claim also recites "means, such as a cassette" which is the narrower statement of the range/limitation.

Remarks

Claims 1-14, as now recited, are free of prior arts.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 19, 2005

Christopher L. Chin
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